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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,544	01/05/2004	Lucien Alfred Couvillon JR.	02-076 C1	2414

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EXAMINER	
ROANE, AARON F	
ART UNIT	**PAPER NUMBER**
3739	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/751,544	COUVILLON, LUCIEN ALFRED	
	Examiner	Art Unit	
	Aaron Roane	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,10-23 and 35-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-23 and 35-39* is/are rejected.

7)☒ Claim(s) *8 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *200503211* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-7, 10-23 and 35-39 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-45 of prior U.S. Patent No. 6,679,836 B2. This is a double patenting rejection.

It should be noted that claims 8 and 9 of the present invention are not rejected under statutory type (35 U.S.C. 101) double patenting. Additionally any non-statutory rejection the examiner could make has been obviated by the filing of the terminal disclaimer filed 1/11/2005.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-7, 12-21, 23, 25-31, 33, 34 and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belson (USPN 6,468,203 B2) in view Madden et al. (USPN 6,249,076 B1).

Regarding claims 1, 14, 23, 25 and 26, Belson discloses providing a guide catheter comprising a plurality of electrically controlled actuators (1, 2, 3, ..., 10) controllable to impart a desired orientation "that allows it to negotiate torturous curves along a desired path", see col. 5, lines 36-62 and abstract. Belson also discloses a sensing system comprising a light source (128) and a camera (126), col. 4, lines 1-9. Belson discloses the insertion of the endoscope into a body lumen while controlling said actuators to impart the desired orientation to the elongated endoscope body, see col. 5, lines 36-62, col. 6 and 7 and the abstract. Belson also discloses a control unit (140) coupled to said plurality of actuators and sending said control signals to said plurality of actuators. Belson does not specifically recite that the actuators are electroactive polymeric actuators. Belson discloses a variety of different types of linear actuators including "electromechanical" actuators, see col. 5, lines 49-52. Madden et al. (see abstract and

figures 1-4) disclose electroactive polymeric actuators. Although Madden et al. do not specifically mention the use of electroactive polymeric actuators in endoscopes and/or provide a motivation, the fact that Belson listed a variety of linear actuators and specifically recited other known "electromechanical" actuators, which is interpreted to include electroactive polymeric actuators, provides proper motivation for combining Belson with the Madden et al. reference. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Belson, as taught by Madden et al., to specifically use electroactive polymeric actuators as another known "electromechanical" actuator.

Regarding claims 4, 5, and 36-39, Belson discloses that each tubular segment of the endoscope comprises 4 actuators. It is inherent in the tubular structure of the endoscope and its function that the actuators will be in tension with each other during the various contortions of the endoscope. Belson also discloses that the actuators cover at least 25% of the fully inserted axial length of the guide catheter/endoscope, see col. 5 and 6 and figures 6 and 7. Finally, Belson discloses that "when configured for use as a colonoscope, the body 102 of the endoscope 100 is typically from 135 to 185 and approximately 12-13 mm in diameter," see col. 3, lines 62-65.

Regarding claim 6, Belson in view of either Madden et al. disclose the claimed invention. Madden et al. disclose electroactive polymeric actuators comprising an active member portion (12), a counter-electrode portion (18) and an electrolyte (14) disposed between

the active member portion and the counter-electrode portion, see Madden et al. starting on col. 2, line 65 and ending on col. 5, line 2 and figures 1 and 2.

Regarding claim 7, Belson in view of either Madden et al. disclose the claimed invention. Madden et al. further disclose electroactive polymeric actuators wherein the active member portion (12), the counter-electrode portion (18) and the electrolyte (14) layers are between a substrate layer (right strip of 22 in figure 2) and a barrier layer (left strip of 22 in figure 2), see Madden et al. col. 6, lines 22-36 and figures 1 and 2.

Regarding claim 12, Belson in view of Madden et al. disclose the claimed invention except for the each actuator being connected to a controlling device (140) by way of an individual cable or by way of a multiplexed cable. However, the connecting of the actuators to the controlling device is inherently either individual or multiplexed, since these are the only two ways in which to connect the actuators to the controlling device. Where there is a limited universe of potential options, the selection of any particular option would have been obvious to one of ordinary skill in the art. In re Jones, 412 F.2d 241, 162 USPQ 224 (CCPA 1969). Therefore, at the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art to use individual cables or a multiplexed cable in order to connect the actuators to the controlling device.

Regarding claim 13, Belson discloses a control unit (140) in the form of a personal computer, see Belson col. 4, lines 9-23.

Regarding claim 15, Belson further discloses a control unit that provides user selectable shape control signals, see Belson, col. 4, lines 9-23.

Regarding claim 16, Belson further discloses a control unit (140) that stores in an electronic memory user selectable shapes, see Belson col. 7, lines 50-54.

Regarding claims 17 and 27, Belson further discloses a manual steering system that is operated under image guidance, see col. 2, lines 17-30. In particular, see the "joystick" steering mechanism (122) in figure 2.

Regarding claims 18 and 28, Belson further discloses control signals generated by a shape-generating algorithm within the control unit using medical diagnostic imagining data, see Belson col. 8, lines 39-67 and col. 9, lines 1-18.

Regarding claims 19 and 29, Belson discloses that the medical diagnostic imaging data is in the form of an angiogram (fluoroscopy and radiography), see starting on col. 8, line 39 and ending on col. 9, line 18.

Regarding claims 20 and 30, Belson further discloses a lead module and a plurality of subsequent modules, and wherein the endoscope is adapted to travel through the lumen in such a way that, when each subsequent module reaches a position in the lumen previously occupied by said lead module, said actuators cause each subsequent module to replicate the orientation of the lead module at said position, see col. 2, lines 31-48 and col. 6, lines 17-56 and figures 7-13.

Regarding claims 21 and 31, Belson discloses a depth gauge and a linear displacement module (or transducer) in the form of an "axial motion transducer" (150) that measures the axial motion of the endoscope body, see col. 4, lines 24-41.

Regarding claims 33 and 34, Belson discloses the guide catheter in a number of selectable shapes at a number of locations in figures 8-13. Furthermore, certain actuators must be activated or in tension with one another for the selectable shapes to be obtained and in this sense, the guide catheter portion is stiffened upon reaching a location determined by an observer, see Belson starting on col. 6, line 66 and ending on col. 8, line 20 and figures 8-13.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belson (USPN 6,468,203 B2) in view of Madden et al. (USPN 6,249,076 B1) as applied to claim 1 above, and further in view of Madden et al. "Polypyrrole actuators: modeling and performance", Proceedings of SPIE, Bar-Cohen ed., Vol. 4329, pages 72-83, March 5-8, 2001.

Regarding claims 2 and 3, Belson in view of Madden et al. disclose the claimed invention except for the explicit use of polyaniline, polyacetylene and specifically polypyrrole within the electroactive polymer actuators. Madden et al. disclose electroactive polymer actuators and teach the explicit use of polypyrrole therein in order to avoid unpredictability of other types actuators using other polymers, see page 72, lines 19-22 and the abstract. Therefore at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Belson, as taught by Madden et al. to specifically use the polymer polypyrrole in order to better "measure, describe and predict the behavior" of the actuators.

Claims 10, 22 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belson (USPN 6,468,203 B2) in view of Madden et al. (USPN 6,249,076 B1) as applied to claim 1 above, and further in view of Shan (USPN 5,957,833).

Regarding claim 10, Belson discloses the claimed invention except for reciting a plurality of strain gauges. Shan discloses a device for special imagining of endoscopes and teaches the use of a plurality of strain gauges (30) to provide endoscopic curvature information in order to provide instantaneous generation of a three-dimensional image of the endoscope, see col. 3, lines 39-50, the abstract and figures 1 and 3. Additionally, the provision of strain gauges by Shan would provide orientation data on the lead module. Therefore at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Belson, as taught by Shan, to use of a plurality of

strain gauges to provide endoscopic curvature information in order to provide instantaneous generation of a three-dimensional image of the endoscope.

Claim 11, 12 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belson (USPN 6,468,203 B2) in view of Madden et al. (USPN 6,249,076 B1) as applied to claim 1 above, and further in view of Takayama et al. (USPN 5,624,380).

Regarding claim 11, Belson discloses the claimed invention except for explicitly reciting a tubular interconnected system of articulable segments. Takayama et al. disclose a multi-degree of freedom manipulator and teach the inclusion of a plurality of structural elements in the form of short tubular "articulated bodies" (7a and 7b), wherein the actuators are attached to pairs of structural elements, and that a restoring force may be applied by placing "return springs" (99) in between the articulable bodies in order that the bodies to be selectively flexed so that a multi-degree-of-freedom manipulator may be realized and so that when the all of the actuators are not being actuated or are at their rest configuration the endoscope maintains a substantially linear configuration, see col.1, lines 51-63, col. 5, lines 38-49, col. 14, lines 4-31 and figures 3 and 26A. Therefore at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Belson, as taught by Takayama et al. to include a plurality of structural elements in the form of short tubular "articulated bodies" and further providing a restoring force by placing "return springs" in between the articulable bodies in order for the bodies to be selectively flexed so that a multi-degree-of-freedom manipulator may be

realized and so that when the all of the actuators are not being actuated or are at their rest configuration the endoscope maintains a substantially linear configuration and to dispose the actuators directly on or within a flexible sheet that forms a sheath body in order to provide a bending means and capability for the sheath body.

Regarding claims 12 and 35, Belson in view of either Madden et al. disclose the claimed invention except for use of a wireless interface to send control signals to the actuators and/or the use of a multiplex connection for the actuators. Takayama et al. disclose a multi-degree of freedom manipulator and teach the inclusion of providing the actuators (41) with control signals via a wireless interface (42 and 44a). Takayama et al. teach that this wireless embodiment is an alternate means of providing control signals to the actuators. The other means comprises two control signal wires (36 and 37) that connect all of the actuators to the controller in order to receive control signals. Both of these control means provide the guide catheter portion with a reduced diameter, see col. 1, and starting on col. 7, line 47 and ending on col. 8, line 44 and figures 9-11. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Belson in view of either Madden et al., as taught by Takayama et al., to provide the actuators with control signals via a wireless interface as an alternate actuator control means that provides the guide catheter portion with a reduced diameter.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Belson (USPN 6,468,203 B2) in view of either Madden et al. (USPN 6,249,076 B1) as applied to claims 1 and 23 above, and further in view of Wilk (USPN 5,535,759).

Regarding claim 24, Belson in view of either Madden et al. disclose the claimed invention except for the step of inserting an interventional device through the guide catheter portion. Wilk discloses an endoscopic method and teaches the use of providing the endoscope with a variety of insertable instruments (each one of these insertable instruments being interpreted as an interventional device) in order to facilitate endoscopic surgery and reduce the time necessary for the endoscopic surgery, see col. 1, lines 61-65. Additionally, Wilk discloses that a either a electrocautery snare may be used in order to remove a polyp or a laser transmitting optical fiber used to treat ulcers, see col. 3, lines 17-33 and in general all figures 1-10F. This is particularly relevant since Belson discloses placement of the guide catheter portion within the colon, see Belson figures 8-13. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Belson in view of either Madden et al., as taught by Wilk, to provide the guide catheter portion with a variety of insertable instruments (each one of these insertable instruments being interpreted as an interventional device) in order to facilitate endoscopic surgery and reduce the time necessary for the endoscopic surgery.

Allowable Subject Matter

Claims 8 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 1/11/2005 have been fully considered but they are not persuasive.

On page 7, paragraph 6 of the response, Applicant suggests that the Belson reference is used as a "shotgun" reference and points out that no where in Belson is there "evidence that electroactive polymer actuators were considered by patentee." Belson does not specifically recite that the actuators are electroactive polymeric actuators. Belson discloses a variety of different types of linear actuators including "electromechanical" actuators, see col. 5, lines 49-52. Madden et al. (see abstract and figures 1-4) disclose electroactive polymeric actuators. Although Madden et al. do not specifically mention the use of electroactive polymeric actuators in endoscopes and/or provide a motivation, the fact that Belson listed a variety of linear actuators and specifically recited other known "electromechanical" actuators, which is interpreted to

include electroactive polymeric actuators, provides proper motivation for combining Belson with the Madden et al. reference.

On page 7, paragraph 7 of the response, Applicant suggests that since Madden et al. disclose only a two actuator mechanical device using electroactive polymer acturators this is not evidence that electroactive polymer acturators could be used in "great numbers in a colonoscope (Belson)." The conclusion of this argument is curious in that Belson uses a large or great number of actuators and that if one were to conclude that after the combination of Belson and Madden et al., it were established that electroactive polymer actuators were to be used in Belson, there in no motivation for using large numbers of them. The examiner can only respond by saying that it seems obvious that anyone of ordinary skill in the art regarding Belson, which discloses a colonoscope with a large number of actuators and a wide variety of type of linear actuators and Madden et al., who disclose the specific use of electroactive polymer actuators would immediately come to a conclusion that electroactive polymer acturators could be used in "great numbers in a colonoscope."

On page 8, Applicant requires an explanation of the inherency of actuators being in tension with each other. This is simple enough and the examiner will provide the explanation of this inherency. Belson in view of Madden et al. disclose a colonoscope having a large number of electroactive polymer actuators. Belson discloses that these actuators "allows it to negotiate torturous curves along a desired path". In other words, the colonoscope may bend in many different directions at a plurality of locations along its length at different times, the same time or

in a particular sequence. When the colonoscope is bending in several different directions at several locations at the same time, one or more of the actuators in the group of four actuators is actuating or pushing (or pulling) while one or more of the actuators in that group of four actuators is not actuating or pushing (or pulling), so within that group of four actuators the actuators are in tension with each other.

On page 8, line 8, Takayama et al. disclose a plurailty of control signal transmission techniques and teach that they are alternate and equivalent forms. Additionally, Applicant has failed to address the "limited universe of potential options" 103 rejection to claim 12, relying only on Belson in view of Madden et al..

On page 8, Applicant traverses the rejections to claims 2 and 3. These claims were rejected using references supplied by Applicant. These references speak directly the use and construction of electroactive polymer actuators and have earlier filing dates than the present claimed invention. The argument that hindsight was used to reject these claims is unpersuasive.

On page 8, Applicant traverses the rejections to claims 10 and 22 and also suggests hindsight reconstruction by the examiner. This argument is extremely unpersuasive in view that the rejection cites specific passages that support and motivate the combination. Additionally, imaging and determining the location and orientation of the endoscope is clearly disclosed in all the references but Madden et al., which further supports the combination since imaging and determining the location and orientation of the colonoscope is paramount in Belson.

On page 8, second to the last line through page 9, second line, Applicant traverses the rejection to claims 11, 12 and 35 as inappropriate "bits and pieces". The examiner would agree if one were simply take everything taught and disclosed in every reference provided by the examiner and lumped them together without any regard whatsoever duplication, redundancy or mix matches of function or modality. However, very rarely does an examiner intend to perform this mass 103 obviousness rejection, and even rarer is it possible to do such a mass 103 obviousness rejection. No, in the present case the examiner clearly points out what is lacking the primary reference(s) and what is disclosed and taught by the secondary reference (Takayama et al. in the present case) and why the combination is well motivated. Again the argument of hindsight and "bits and pieces" is unpersuasive.

Due to the new rejection under statutory type (35 U.S.C. 101) double patenting to claims 1-7, 10-23 and 35-39, this action is non-final.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. A. R.
March 21, 2005

John P. Loubecker
Primary Examiner